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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,861	07/03/2002	Carlos Cordon-Cardo	55293-B-PCT-US/JPW/FHB	6709

7590 10/24/2003

Cooper & Dunham
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
SOUAYA, JEHANNE E	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,861	CORDON-CARDO ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1,2,4-6,9-16,18,19,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4-6,9-16,18,19,25 and 26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4, and 11, drawn to a method for determining the aggressiveness of a prostate carcinoma, diagnosing benign prostate hyperplasia, predicting the life span of a patient with prostate carcinoma by detecting the presence of p27 RNA or protein; and a nucleic acid molecule encoding a p27 protein.

Group II, claim(s) 5-8, drawn to methods involving gene therapy to increase or prolong the life span of a patient with prostate carcinoma by inducing expression of p27 protein or introducing nucleic acid encoding p27 protein.

Group III, claim(s) 9, drawn to a method for prolonging the life span of a patient with prostate carcinoma by introducing p27 protein.

Group IV, claim(s) 10, drawn to a method for prolonging the life span of a patient with prostate carcinoma by introducing a substance that stabilizes a p27 protein.

Group V, claim(s) 12, drawn to p27 protein.

Group VI, claim(s) 13, drawn to a substance that stabilizes p27 protein.

Group VII, claim(s) 14, drawn to a method for determining the rate of proliferation of prostate cancer by detecting the presence of p21 protein, drawn to.

Group VIII, claim(s) 15, drawn to a method for determining the rate of proliferation of prostate cancer by detecting the presence of mdm2 overexpression.

Group IX, claim(s) 16, drawn to a method for determining whether a prostate cancer is metastatic by detecting the overexpression of cyclin D1.

Group X, claim(s) 18, drawn to a method for detecting tumor recurrence by detecting the over expression of p16.

Group XI, claim(s) 19, drawn to a method of treating prostate cancer by administering anti-Her/neu antibody.

Group XII, claim(s) 25-26, drawn to methods of diagnosing prostate cancer by measuring Her-2/neu expression.

2. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The p27 protein and nucleic acid encoding were known in the prior art at the time of the invention. In addition:

Group I, claims 1-4, 11 form a single inventive concept of a method of diagnosis of prostate cancer by detecting p27 protein or mRNA, or both and a composition comprising a nucleic acid molecule encoding p27 protein.

Group II, claims 5-8, is an additional method of use for the claimed p27. That is, treating a patient using gene therapy, by administering a p27 polynucleotide. The objective and the means of the method of group II is distinct from those of group I, that is treating prostate cancer versus diagnosis of cancer, and administration of p27 polynucleotide versus detection of the expression p27.

Group III, claim 9 is an additional method of use for p27, i.e. treating a patient by administering a p27 protein. The objective of group III is distinct from that of group I, i.e. treating prostate cancer versus diagnosis of cancer. Furthermore, the steps of the method of group IV are distinct from those of groups I and II, that is administering p27 protein versus detecting the presence of p27, and administering p27 polynucleotide, respectively.

Group IV, claim 10, is a method of treating a patient by administering a substance capable of stabilizing p27 protein. The objective of group IV is distinct from that of group I. That is, treating prostate cancer versus diagnosis of cancer. Furthermore, the steps of the method of group IV (administering a substance capable of stabilizing p27 protein), is distinct from those of groups I, II and III: detecting the presence of p27, administering p27 polynucleotide and administering p27 protein, respectively.

Group V, claim 12, drawn to p27 protein, which is structurally and functionally distinct from p27 polynucleotide of group I.

Group VI, claim 13, drawn to a substance capable of stabilizing p27 protein which is structurally distinct from p27 polynucleotide of group I.

Group VII, claim 14, is an additional method of determining the rate of prostate cancer proliferation by detecting p21 protein. Group VII is distinct from group I because reagents used in group VII are different from that of group I. i.e. using p27 versus p21 protein. Furthermore

since p27 is known in the art (US 5688665), p27 is not novel to form a link for a single general inventive concept.

Group VIII, claim(s) 15, drawn to a method for determining the rate of proliferation of prostate cancer by detecting the presence of mdm2 overexpression, which uses different reagents (mdm2 vs p27) from the method of diagnosis of group I.

Group IX, claim(s) 16, drawn to a method for determining whether a prostate cancer is metastatic by detecting the overexpression of cyclin D1, which has a different objective (diagnosing cancer vs detecting metastasis) and uses different reagents (cyclin D1 vs p27) than the method of diagnosis of group I.

Group X, claim(s) 18, drawn to a method for detecting tumor recurrence by detecting the over expression of p16, which has a different objective (detecting tumor recurrence vs diagnosis) and uses different reagents (p16 vs p27) than the methods of diagnosis of group I.

Group XI, claim(s) 19, drawn to a method of treating prostate cancer by administering anti-Her/neu antibody is distinct from the method of group I in that the objective is different (treating vs diagnosis) and the reagents (anti Her-2/neu vs p27) are different. Further, the method is distinct from groups II and III in that the reagents (anti-Heu-2/neu vs p27 nucleic acid or p27 protein) are structurally and functionally distinct.

Group XII, claim(s) 25-26, drawn to methods of diagnosing prostate cancer by measuring Her-2/neu expression which is distinct from the method of diagnosis of group I in that the reagents (Her-2/neu vs p27) are structurally and functionally distinct.

3. A telephone call was made to Maria Maruchi on October 20, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made as applicant's representative requested the restriction requirement in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Primary Examiner
Art Unit 1634
10/22/03